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PTO/SB/05 (11-00)

Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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# UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))

Attorney Docket No. 16602.003

First Inventor MICHELSON, et al.

Title Systems and Methods for Selecting and Recruiting Investigators and Subjects for Clinical Studies

Express Mail Label No.

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.  
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 104]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross References to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to sequence listing, a table, or a computer program listing appendix
  - Background of the invention
  - Brief Summary of the invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 89]
5. Oath or Declaration [Total Pages]
  - a. ☐ Newly executed (original or copy)
  - b. ☐ Copy from a prior application (37 CFR 1.63 (d))  
(for a continuation/divisional with Box 18 completed)
  - i. ☐ **DELETION OF INVENTOR(S)**  
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
6. ☐ Application Data Sheet. See 37 CFR 1.76

## ADDRESS TO:

Assistant Commissioner for Patents  
Box Patent Application  
Washington, DC 20231

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
  - a. ☐ Computer Readable Form (CRF)
  - b. Specification Sequence Listing on:
    - i. ☐ CD-ROM or CD-R (2 copies); or
    - ii. ☐ paper
  - c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATIONS PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 C.F.R. §3.73(b) Statement ☐ Power of Attorney  
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)
16. ☐ Request and Certification under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a **CONTINUING APPLICATION**, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP)

of prior application No: PCT / US01/02936

Prior application information: Examiner \_\_\_\_\_

Group / Art Unit: .....

For **CONTINUATION** or **DIVISIONAL** APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

## 17. CORRESPONDENCE ADDRESS

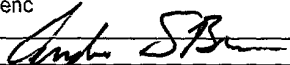
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or ☐ Correspondence address below

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Name (Print/Type)	Joseph A. Micallef/ Andrew S. Brenc	Registration No. (Attorney/Agent)	39,772/45,534
Signature		Date	August 8, 2001

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

# ARNOLD & PORTER

August 8, 2001

## ***Box Patent Application***

Commissioner for Patents  
Washington, D.C. 20231

Re: Continuation Application Based on PCT/US01/02936  
filed on January 29, 2001  
Appl. No.: To Be Assigned  
Filed: Herewith  
For: Systems and Methods for Selecting and Recruiting Investigators  
and Subjects for Clinical Studies  
Inventors: MICHELSON, *et al.*  
Atty. Docket: 16602.003

Sir:

The following documents are forwarded herewith for appropriate action by the U.S.  
Patent and Trademark Office:

1. Utility Patent Continuation Application Transmittal form PTO/SB/05;
2. U.S. Continuation Application entitled:

### **Systems and Methods for Selecting and Recruiting Investigators and Subjects for Clinical Studies**

and naming as inventors:

Leslie D. MICHELSON, Leonard ROSENBERG, and Lance CONVERSE;

the application consisting of:

- a. A specification containing:
  - (i) 64 pages of a description prior to the claims;
  - (ii) 39 pages of claims (120 claims);
  - (iii) 89 pages of drawing; and
  - (iv) a one (1) page abstract;

Variable	Mean	SD	Min	Max
Age	34.5	10.2	21	55
Gender	Male	100%		
Marital status	Married	100%		
Education	High school	100%		
Occupation	Farmer	100%		
Income	Low	100%		
Health status	Good	100%		
Smoking status	Non-smoker	100%		
Alcohol consumption	None	100%		
Family size	4.5	1.5	2	8
Household size	5.5	1.5	3	9
Land area	2.5	1.0	1	4
Water availability	Good	100%		
Soil fertility	Medium	100%		
Climate	Temperate	100%		
Topography	Flat	100%		
Vegetation	Deciduous forest	100%		
Wildlife	Low	100%		
Human population	Low	100%		
Infrastructure	Basic	100%		
Healthcare	Basic	100%		
Education	Basic	100%		
Employment	Low	100%		
Income	Low	100%		
Health status	Good	100%		
Smoking status	Non-smoker	100%		
Alcohol consumption	None	100%		
Family size	4.5	1.5	2	8
Household size	5.5	1.5	3	9
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Topography	Flat	100%		
Vegetation	Deciduous forest	100%		
Wildlife	Low	100%		
Human population	Low	100%		
Infrastructure	Basic	100%		
Healthcare	Basic	100%		
Education	Basic	100%		
Employment	Low	100%		
Income	Low	100%		
Health status	Good	100%		
Smoking status	Non-smoker	100%		
Alcohol consumption	None	100%		

Commissioner for Patents  
Atty. Dkt.: 16602.003  
Page 2

3. Preliminary Amendment;
4. 114 sheets of Formal Drawings (Figs. 1A-1B, 2A-2B, 3, 4A-4D, 5A-5J, 6A-6R, 7A-7J, 8A-8B, 9A-9B, 10A-10B, 11A-11B, 12-14, 15A-15H, 16-20, 21A-21Q, 22A-22P, 23, 24A-24E, 25, 26A-26B and 27);
5. Check No. 200567 in the amount of \$355.00 to cover small entity filing fee;
6. Information Disclosure Statement along with PTO Form-1449 listing 8 references;
7. Copies of the 8 references listed on PTO Form 1449;
8. Petition to Make Special Under 37 C.F.R. §1.102;
9. Check No. 200563 in the amount of \$130.00 to cover petition fee; and
10. Two (2) return postcards.

Pursuant to 35 U.S.C. §120, this application claims priority to and is a continuation of PCT/US01/02936, which claims priority to US Provisional Application 60/178,634, filed January 28, 2000, under 35 USC §119(e).

Application PCT/US01/02936 is herein incorporated by reference in its entirety. Please stamp the prepaid postcard with the filing date and unofficial application number and return as soon as possible, and stamp the other postcard with the filing date of these documents and return to our courier.

